

### REMARKS

Claims 1 to 9 are pending in present application. Claims 1 to 9 have been rejected under 35 U.S.C. § 112 first paragraph and 35 U.S.C. § 112 second paragraph. Claim 1 has been amended, and the rejections to claims 1 to 9 are traversed below. By way of these amendments no new matter has been added.

#### Rejection of Claims 1 to 9 under 35 U.S.C. § 112 first paragraph

The Examiner rejected claims 1 to 9 under 35 U.S.C. § 112 first paragraph for failing to comply with the written description requirement. It was noted that the claims contain subject matter, that is, "oxime functions", "amide functions" and "or prophylaxis", which are not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventors, at the time the application was filed, had possession of the claimed invention. Additionally, the Examiner rejects claims 1 to 9 under 35 U.S.C. § 112 first paragraph because the specification while being enabling for method of treating bacterial infection using a compound of formula (I), wherein alkyl of the variable R<sup>3</sup> is substituted with amide or oxime, does not reasonably provide enablement for a method of preventing (prophylaxis of) bacterial infection using a compound of formula (I).

Applicants have amended claim 1 to delete the word "functions". This restricts substituents on the alkyl and alkenyl groups to CN, amide and oxime and on the aryl group to CN and amide. The meaning of the terms amide and oxime are well known to the skilled person. See *IUPAC Compendium of Chemical Technology, 2<sup>nd</sup> Edition (1997)* (copy from IUPAC website attached).

Regarding the rejection based upon the lack of enablement provided by the specification for the term "prophylaxis" (prevention of bacterial infections), Applicants' disagree with the Examiner's assessment. It is very well known in the art that compounds that possess antibacterial activity are routinely used prophylactically. Thus, in the medical arts, it is well known that antibiotic compounds are considered to be useful as both curative medicines, for acquired bacterial infections, as well as preventive medicines, that is, to protect against bacterial infections.

*In re Howarth* supports the principle that enablement under the first paragraph of § 112 may be satisfied using information found in the prior art and the CCPA has written the following: "It is well understood that the disclosure of an application embraces not only what is expressly set forth in words or drawings, but what would be understood by persons skilled in the art. As was said in *Webster Loom Co. v. Higgins et al.*, 105 U.S. 580,586, the applicant 'may begin at the point where his invention begins, and describe what he has made that is new and what it replaces of the old. That which is common and well known is as if it were written out in the patent and delineated in the

drawings.” See *In re Howarth* 692 F.2d 103, 210 USPQ 689 (C.C.P.A.) (quoting *In re Chilowsky*, 229 F.2d 457, 460, 108 USP 321, 324 (C.C.P.A.)). Furthermore, the MPEP at 2164.05(a) states “The specification need not disclose what is well-known to those skilled in the art and preferably omits that which is well-known to those skilled and already available to the public.”

A search of the prior art uncovers many references, which are readily available to the public, that teach how to use antibiotics to prevent bacterial caused infections. Applicants attach the following references to support the contention: Beers, M. H. et al., ed. Antimicrobial Chemoprophylaxis. In, *The Merck Manual of Diagnoses and Therapy*, 17<sup>th</sup> Edition, Merck Research Laboratories, Whitehouse Station, NJ, 1999, pp. 1123-1127; Sande, M. A. and Mandell, G. L. Chemotherapy of Microbial Diseases, Chapter 48 Antimicrobial Diseases. In *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 7<sup>th</sup> Edition, Macmillan Publishing Co., New York, 1985, pp. 1089-1090; Blank, S. et al. An Ounce of Prevention Is a Ton of Work: Mass Antibiotic Prophylaxis for Anthrax, New York City, 2001. *Emerging Infectious Diseases*, 2003, 9 615-622; Cruciani, M. Antibacterial Prophylaxis. *International Journal of Antimicrobial Agents*, 16 (2000) 123-125. Thus, it seems apparent by way of these readily accessible references, the skilled person could practice this aspect of the invention without any undue experimentation.

In view the amendments and the arguments advanced above, Applicants respectfully submit that claims 1 to 9 fully satisfy the requirements of 35 USC § 112 first paragraph and therefore, request withdrawal of rejection as to claims 1 to 9.

#### Rejection of Claims 1 to 9 under 35 U.S.C. § 112 second paragraph

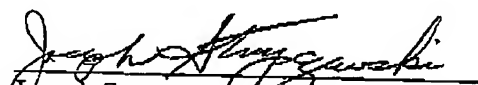
The Examiner rejected claims 1 to 9 under 35 U.S.C. § 112 second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention. The Examiner cited the terms “amide functions” and “oxime functions” as ambiguous and indefinite. As presented above, Applicants have amended claim 1 to delete the word “functions”. This restricts substituents on the alkyl and alkenyl groups to CN, amide and oxime and on the aryl group to CN and amide. The meaning of the terms amide and oxime are well known to the skilled person. Therefore, based upon this amendment Applicants respectfully request withdrawal of the rejection to claim 1 as being indefinite under 35 U.S.C. § 112 second paragraph.

Conclusion

In view of the Amendments and Remarks presented herein Applicants respectfully submit that the claims 1 to 9 are now in condition for allowance and respectfully request a notice to this effect. Should the Examiner have any questions please call (collect if necessary) the undersigned attorney at the telephone number listed below.

Applicant believes that there are no fees due for this Rule 111 Amendment. However, if the Commissioner deems that fees are due, please charge these fees to Deposit Account No. 18-1982 for Aventis Pharmaceuticals Inc., Bridgewater, NJ. Please credit any overpayment to Deposit Account No. 18-1982.

Respectfully submitted,

  
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Aventis Docket No. DEAV2001/0061 US NP

Attachments: *IUPAC Compendium of Chemical Technology*, 2<sup>nd</sup> Edition (1997); *The Merck Manual of Diagnoses and Therapy*, 17<sup>th</sup> Edition, Merck Research Laboratories, Whitehouse Station, NJ, 1999, pp. 1123-1127; Sande, M. A. and Mandell, G. L. Chemotherapy of Microbial Diseases, Chapter 48 Antimicrobial Diseases. In *Goodman and Gilman's The Pharmacological Basis of Therapeutics*, 7<sup>th</sup> Edition, MacMillan Publishing Co., New York, 1985, pp. 1089-1090; Blank, S. et al. An Ounce of Prevention Is a Ton of Work: Mass Antibiotic Prophylaxis for Anthrax, New York City, 2001. *Emerging Infectious Diseases*, 2003, 9 615-622; Cruciani, M. Antibacterial Prophylaxis. *International Journal of Antimicrobial Agents*, 16 (2000) 123-125.

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